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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/777,639 | 02/07/2001 | Babak Nemati | | 7136 |

7590 05/14/2003

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EXAMINER

HAYES, MICHAEL J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3763

DATE MAILED: 05/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/777,639

Applicant(s)

NEMATI, BABAK

Examiner

Michael J Hayes

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 70-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 3763

DETAILED ACTION

Claim Renumbering

Newly submitted claims 17-31 have been renumbered 70-84 due to the presence of canceled claims 17-69 in the application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 70, 71, 74, 75 and 76 are rejected under 35 U.S.C. 102(e) as being anticipated by CHAN et al.. Chan discloses a method of delivering a glycerol clarifying agent past a surface permeability layer of skin to covered biological tissue to enhance optical transparency. Chan discloses the agent as used in treatment of patients (1: 13-21). Chan's delivery includes jet injection which applies physical force to the agent to force it through the barrier layer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 3763

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 72, 83, and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHAN in view of EDWARDS (U. S. Patent No. 5,833,647). Chan discloses the claimed invention except for delivery of an agent past barrier tissue by sonophoresis, electroporation, temperature gradient, or iontophoresis. Edwards teaches the use of these methods to delivery drugs past barrier tissue for treatment of a patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Edwards in the method of Chan in order to effectively deliver an agent past the barrier tissue.

Claims 73 and 77-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHAN in view of WEAVER et al. (U. S. Patent No. 5,019,034). Chan discloses the claimed invention except for using concentration gradient, optical pressure, or solvent to deliver the agent past barrier tissue. Weaver teaches the use of concentration gradient is well known in the art (2:3-10). Weaver also teaches the methods of optical pressure to drive molecules across skin barrier and penetrating solvents, such as dimethyl sulfoxide, to increase skin permeability to aid agents to pass the skin barrier (2:20-26). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Weaver in the invention of Chan in order to effectively deliver fluids past the skin barrier to achieve treatment.

Claims 83 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHAN in view of Henry et al. (J. Pharm. Sci. 87(8) pp 992-925). Chan discloses the claimed invention except for delivering the agent using microneedles to increase the skin permeability. Henry discloses using microneedles to deliver agents past the stratum corneum. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of

Art Unit: 3763

Henry in the invention of Chan in order to effectively deliver molecules to tissue covered by the stratum corneum barrier.

Response to Arguments

Applicant argues that Chan does not disclose causing a clarifying agent to bypass the surface permeability layer to enhance the optical transparency of tissue, only disclosing “replacement fluid.” The examiner does not agree and maintains that Chan discloses bypassing the surface layer via jet injection to deliver glycerol to covered tissue to enhance optical transparency (1:1-4:12). Whether the glycerol replaces fluid is immaterial. The claims read on the prior art. Applicant has not addressed any issues of replacement fluid with limitations in the claims.

Applicant argues that Edwards, Weaver, and Henry address different problems than Chan and deliver agents for different reasons and therefore there is no motivation to combine the references. The examiner disagrees and maintains that all the references are concerned with methods to bypass the barrier layer of skin to deliver agents to covered tissue. The references show that it is well known in the art to use different methods to achieve this delivery. One of ordinary skill in the art would know by these references of the availability and desirability of the different methods, each having its own benefits.

Applicant characterizes the glycerol delivered by Chan as non-therapeutic. The examiner disagrees because Chan discloses that the glycerol is used to assist in diagnoses and treatment (1:21). In a reasonable and broad interpretation of “therapeutic” glycerol is considered therapeutic because it is related to, and assists, in the treatment of patients. Regardless of the characterization of glycerol, all the references are concerned with the same problem of delivering

Art Unit: 3763

agents across the skin barrier and the various methods recited in the claims are shown to be well known established methods of delivering agents to covered tissue.

Applicant mentioned possibility of an interview in his last paper, received 2/28/03. If Applicant desires an interview he should contact the examiner and arrange a date and time for one.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be

Application/Control Number: 09/777,639

Page 6

Art Unit: 3763

contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9302.

The fax number for submitting after final papers is (703) 872-9303.

mjh
12 May 2003

A handwritten signature in black ink that reads "Michael J. Hayes". The signature is written in a cursive, flowing style.

MICHAEL J. HAYES
PRIMARY EXAMINER